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<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	09/839,778
	Filing Date	April 20, 2001
	First Named Inventor	Herron et al.
	Group Art Unit	1641
	Examiner Name	A. Lam
Attorney Docket Number		0274.02-3278.1US

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<input checked="" type="checkbox"/> Second Appeal Brief in response to office action dated November 17, 2004	<input type="checkbox"/> Petition	
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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT		
Firm or Individual name	Brick G. Power	Registration No. 38,581
Signature	<i>Brick G. Power</i>	
Date	February 17, 2005	

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**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**In re Application of:**

Herron et al.

**Serial No.:** 09/839,778

**Filed:** April 20, 2001

**For:** DIAGNOSTIC DEVICE AND  
METHOD

**Confirmation No.:** 3373

**Examiner:** A. Lam

**Group Art Unit:** 1641

**Attorney Docket No.:** 0274.02-3278.1US

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**SECOND APPEAL BRIEF**

Mail Stop Appeal Brief – Patents  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Attn: Board of Patent Appeals & Interferences

Sirs:

This Second Appeal Brief is being submitted in triplicate, in the format required by 37 C.F.R. § 41.37(c), and in response to the new grounds of rejection presented in the Office Action dated November 17, 2004.

As explained in the BPAI FAQ – Rules of Practice before the BPAI (effective September 13, 2004), accessible at <http://www.uspto.gov/web/offices/dcom/bpai/fr2004/bpaifaq.html>, at A12, since an Appeal Brief was filed prior to September 13, 2004 and the Examiner reopened

prosecution and issued a non-final Office Action containing a new ground of rejection after September 13, 2004, Appellant can reinstate the appeal by filing a complete new brief in compliance with 37 C.F.R. § 41.37. This Second Appeal Brief is being submitted within three months of the mailing date of the November 17, 2004, Office Action and is in the format required under 37 C.F.R. § 41.37(c), thereby reinstating the appeal.

Any fee required to reinstate the appeal or in connection with this Second Appeal Brief in may be charged to deposit account number 201469.

**I. REAL PARTY IN INTEREST**

The real party in interest in the above-referenced appeal is BioCentrex, LLC, which has received an exclusive license to the technology disclosed and claimed in the above-referenced application from the University of Utah Research Foundation, the named assignee of the above-referenced application, as evidenced by the assignments that have been recorded with the U.S. Patent & Trademark Office at Reel 009243, Frame 0029, on June 8, 1998, and at Reel 009712, Frame 010729, on January 19, 1999.

**II. RELATED APPEALS AND INTERFERENCES**

Appellants are not aware of any related applications that are currently on appeal or the subject interference proceedings that would affect the outcome of this appeal.

III. STATUS OF THE CLAIMS

Claims 1-21 are currently pending and under consideration in the above-referenced application.

Each of claims 1-21 stands rejected.

The rejections of claims 1-21 are being appealed.

IV. STATUS OF AMENDMENTS

The above-referenced application, U.S. Patent application serial no. 09/839,778 (hereinafter "the '778 Application"), was filed on April 20, 2001, as a divisional of the U.S. Patent application serial no. 08/933,203, filed on September 18, 1997. The '778 Application was originally filed with 35 claims.

A Restriction Requirement was mailed on September 11, 2002. Claims 1-35 were subject to the Restriction Requirement.

On December 16, 2002, a Response to the Restriction Requirement was filed with a petition and the appropriate fee for a two-month extension of time. In that Response, an election was made to prosecute claims 1-21 without traverse.

In a Notice to Comply dated February 24, 2003, the Office required that a sequence listing be filed and that the specification be amended to identify all of the listed nucleic acid and peptide sequences.

On April 1, 2003, a Response to the Notice to Comply was filed. The Response indicated that there are no nucleic acid or peptide sequences in the above-referenced application and

requested withdrawal of the demands that a sequence listing and amendments to the specification be filed.

A first Office Action on the merits of claims 1-21 was mailed by the Office on June 30, 2003. Each of claims 1-21 was rejected.

An Amendment was filed in response to the first Office Action on September 30, 2003. That Amendment included several claim revisions, as well as explanations of the patentability of claims 1-21.

On December 31, 2003, a Final Office Action followed. The rejections on the merits of claims 1-21 were maintained.

In an Amendment Under 37 C.F.R. § 1.116, another attempt was made to explain to the Examiner the reasons why claims 1-21 are patentable over the art of record. In addition, minor claim revisions were presented to correct formal errors therein.

The Examiner responded on June 4, 2004, with an Advisory Action. In the Advisory Action, she indicated that the previously proposed claim amendments would be entered, but continued to reject claims 1-21.

Accordingly, a Notice of Appeal was filed on June 30, 2004, with a petition and the appropriate fee for a three-month extension of time.

An Appeal Brief was filed on Monday, September 1, 2004.

The Examiner reopened prosecution and mailed a non-final Office Action on November 17, 2004, in which new grounds of rejection were presented.

This Second Appeal Brief follows the Office Action of November 17, 2004.

V. SUMMARY OF THE CLAIMED INVENTION

The disclosure and claims of the above-referenced application are drawn to methods for performing assays. More specifically, these methods include so-called “kinetic assays” for more than one analyte. Paragraphs [0094] through [0100].

Such a method includes substantially simultaneously evaluating the presence of a plurality of analytes in a sample. Paragraphs [0115] through [0123]; Figs. 16-21. At least one of the evaluated analytes is known to be associated with an acute metabolic state or disease state. *See, e.g.*, paragraph [0092]. The binding kinetics are then evaluated to substantially simultaneously determine concentrations of the analytes. Paragraphs [0094] through [0100] and [0121]. This determination continues until a reliable determination has been made of whether the at least one analyte is present in an amount which is indicative of the acute metabolic state or disease state. Paragraphs [0013], [0099], [0100]. The results are then reported. Paragraph [0100].

The method may be effected as a competition-type assay, a sandwich assay, or otherwise. Paragraph [0087].

The use of waveguide assay techniques is particularly useful for obtaining real-time information on the binding kinetics and, thus, the amount of each analyte in a particular sample. Paragraph [0011]. When such techniques are used, light is internally reflected within the waveguide to generate an evanescent field at a surface of the waveguide. *See, e.g.*, paragraphs [0046], [0050], [0075]. When markers, such as fluorescent dyes, metal labels, or the like, that are used to measure the binding kinetics in the assay enter the evanescent field, they become “excited.” *See, e.g.*, paragraphs [0090], [0091]. The level of excitation may be

measured to facilitate evaluation of the binding kinetics or the amount of a particular analyte in the sample. Paragraphs [0095] through [0100].

By way of nonlimiting example, an assay according to the invention disclosed in the '778 Application may be used to evaluate the cardiac health of an individual. Paragraphs [0116] through [0123]. In such an assay, the presence of a combination of cardiac markers, such as troponin, creatine-kinase, myoglobin, or the like, may be evaluated and considered in quickly (*e.g.*, within a matter of minutes) diagnosing the individual's cardiac health. *Id.*; *see also*, [0010] through [0014].

#### VI. GROUND OF REJECTION TO BE REVIEWED ON APPEAL

The rejections of claims 1-6, 8, 9, 11, and 13-21 under 35 U.S.C. § 102(e) for being directed to subject matter which is purportedly anticipated by the subject matter described in U.S. Patent 5,747,274 to Jackowski (hereinafter "Jackowski"); and

The rejections of claims 7 and 10-12 under 35 U.S.C. § 103(a) for reciting subject matter which is allegedly unpatentable over the subject matter taught in Jackowski, in view of teachings from U.S. Patent 4,224,304 to Sawai et al. (hereinafter "Sawai").

#### VII. ARGUMENT

##### (A) REJECTIONS UNDER 35 U.S.C. § 102(e)

Claims 1-6, 8, 9, 11, and 13-21 stand rejected under 35 U.S.C. § 102(e) for being directed to subject matter which is purportedly anticipated by the subject matter described in Jackowski.

(1) LEGAL AUTHORITY

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single reference which qualifies as prior art under 35 U.S.C. § 102. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Notably, patent applicants are their own lexicographers and, thus, determine the meanings of the various terms that appear in the claims of their patent applications. M.P.E.P. § 2173.01. In this regard, the meaning of every term in a claim should be determined from the descriptive portion of the specification. M.P.E.P. § 608.01(o). “When the specification states the meaning that a term is intended to have, the claim is examined using that meaning . . .” M.P.E.P. § 2173.05(a), citing *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989).

(2) REFERENCE RELIED UPON

*Jackowski*

Jackowski describes that multiple assays for different analytes may be conducted on a single sample that is obtained at a single point in time. Col. 22, lines 12-14. Thus, the amounts of markers that are simultaneously present in the sample may be accurately determined. Col. 22, lines 15-19. Assays for each of the analytes of interest may then be performed within a given time frame after the sample is obtained. Col. 22, lines 7-8.

As used in Jackowski, the term “simultaneous” does not have its ordinary meaning or that used in the specification of the above-referenced application. Rather, as indicated at col. 22,



lines 2-19, the term “simultaneous” is not used in Jackowski to indicate that analysis of different analytes occurs concurrently, but that the analysis occurs within a given period of time (e.g., thirty minutes) and that each analysis is performed on part of the same sample.

The description of Jackowski is also limited to use of different assays on a sample, all of which are conducted within a give window of time, to provide determinations of whether or not multiple analytes are present in the sample at different points in time. Col. 22, lines 2-19; *see also* col. 22, lines 2-12; col. 29, lines 50-63, col. 30, lines 18-26; col. 35, lines 60-68. FIGs. 8 through 10 of Jackowski provide an example in which a sample is assayed for three analytes. Even in this multi-analyte assay, the sample is assayed for each analyte at a different point in time, *i.e.*, depending upon the time it takes the sample to wick, or travel by capillary action, along a membrane 18 to which the sample is applied. Col. 30, lines 63-67; FIG. 9. Specifically, myoglobin (“MYO”) is assayed at a first point in time, creatine kinase-MB (“CK-MB”) is assayed at a later, second point in time, and myosin light chain (“MLC”) is assayed at an even later, third point in time. Col. 30, line 67, to col. 31, line 21; FIG. 10.

### (3) ANALYSIS

Independent claim 1 of the ‘778 Application is directed to a method for performing an assay. The method of independent claim 1 includes, among other things, substantially simultaneously evaluating the presence of a plurality of analytes in a sample. At least one of the plurality of analytes has known parameters that are indicative of an acute metabolic or disease state. In addition, the method of independent claim 1 includes substantially simultaneously determining concentrations of each of the plurality of analytes in the sample. The substantially

simultaneous determination is continued until at least one of the analytes has been reliably determined to be present in an amount that is indicative of a metabolic or disease state. Once the amount of at least one of the analytes has been reliably determined, that determination is reported.

In contrasting the subject matter recited in independent claim 1 to that described in Jackowski, it is apparent that Jackowski does not anticipate several elements of independent claim 1, as would be required to maintain the 35 U.S.C. § 102(e) rejection of independent claim 1.

First, it is respectfully submitted that Jackowski neither expressly nor inherently describes “*continuing* a substantially simultaneous determination” of the presence of at least one analyte in a sample “*until* the at least one analyte has been reliably determined to be present in an amount indicative of a metabolic or disease state . . .” (emphasis supplied). The term “continuing” in independent claim 1 clearly indicates that analysis of the binding of the at least one analyte occurs over a period of time rather than at a single point in time. Stated another way, the kinetics of the binding reactions are evaluated to provide an accurate determination of whether or not one or more analytes is present in a sample and, optionally, the amount of each evaluated analyte in the sample. The description of Jackowski, in contrast, is limited to less accurate “end point” assay techniques, where the amount of each analyte in a sample is determined at a single point in time. Therefore, Jackowski does not anticipate “continuing [a] substantially simultaneous determination until . . . at least one analyte has been reliably determined to be present in an amount indicative of [a] metabolic or disease state . . .”

Second, it is respectfully submitted that Jackowski does not expressly or inherently describe that multiple analytes of a sample may be substantially simultaneously evaluated. The meaning of the term “simultaneously,” as used in independent claim 1, should be determined from the specification of the ‘778 Application rather than from the meaning that Jackowski has supplied for that term. *See* M.P.E.P. §§ 608.01(o); 2173.01; and 2173.05(a). The specification of the above-referenced application, at paragraphs [0072], [0078], and, in particular, [0121], makes it extremely clear that when two or more analytes in a sample are evaluated substantially simultaneously, they are evaluated at substantially the same time, or substantially concurrently. Jackowski, in contrast, clearly indicates that different analytes in a sample need not be evaluated concurrently. Col. 22, lines 6-12. Therefore, Jackowski does not anticipate the element of “substantially simultaneously evaluating the presence of a plurality of analytes in a sample” recited in independent claim 1.

Third, for the same reasons Jackowski does not expressly or inherently describe, or anticipate, “substantially simultaneously evaluating . . .,” it is respectfully submitted that Jackowski does not expressly or inherently describe, or anticipate, “substantially simultaneously determining concentrations of each of the plurality of analytes in the sample,” as is required by independent claim 1.

In view of the foregoing, it is respectfully submitted that, under 35 U.S.C. § 102(e), independent claim 1 recites subject matter which is allowable over that described in Jackowski.

Each of claims 2-21 is allowable, among other reasons, for depending either directly or indirectly from claim 1, which is allowable.

Claim 2 is additionally allowable because Jackowski includes no express or inherent description that “evaluating the presence of at least one other analyte in [a] sample” may *continue* after a report of a reliable determination that at least one analyte in the sample is present in an amount which is indicative of a metabolic or disease state. Again, the description of Jackowski is limited to effecting evaluations of the presence of analytes in a sample at single points in time rather than continuously.

Claim 8 is also allowable because Jackowski does not expressly or inherently describe that a substantially simultaneous determination of the presence of at least one analyte in a sample may be effected by reacting at least one analyte in a sample with a corresponding reactive element, the corresponding reactive element being one of a plurality of reactive elements that are arranged in one or more patterns on the surface of a waveguide.

For these reasons, reversal of the 35 U.S.C. § 102(e) rejections of claims 1-6, 8, 9, 11, and 13-21 is respectfully requested.

(B) REJECTIONS UNDER 35 U.S.C. § 103(a)

Claims 7 and 10-12 stand rejected under 35 U.S.C. § 103(a) for reciting subject matter which is allegedly unpatentable over the subject matter taught in Jackowski, in view of teachings from Sawai.

(1) LEGAL AUTHORITY

The standard for establishing and maintaining a rejection under 35 U.S.C. § 103(a) is set forth in M.P.E.P. § 706.02(j), which provides:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

(2) ADDITIONAL REFERENCE RELIED UPON

*Sawai*

Sawai teaches an agglutination assay technique that includes use of latex particles that have multiple capture molecules secured thereto. Col. 5, line 66, to col. 6, line 6. When mixed with a sample, analyte present in the sample binds to the capture molecules on the latex particles. *Id.* Such binding may be detected by irradiating a solution including the sample and the latex particles (col. 6, lines 6-19), then measuring an amount of the radiation absorbed by the solution (col. 9, lines 3-33). When absorbance measurements are obtained at two or more points in time, the rate of binding may be estimated, which provides an indication of the amount, or concentration, of the analyte in the sample. Col. 9, lines 34-40.

(3) ANALYSIS

Claims 7 and 10-12 are each allowable, among other reasons, for depending indirectly from claim 1, which is allowable.

In addition, it is respectfully submitted that there are at least two reasons that the teachings of Jackowski and Sawai do not support a *prima facie* case of obviousness against any of claims 7 or 10-12.

First, it is respectfully submitted that one of ordinary skill in the art would not have been motivated to combine the teachings of Jackowski and Sawai in such a way as to render the simultaneous, multi-analyte assay method recited in the claims of the above-referenced application obvious. In particular, neither Jackowski nor Sawai teaches or suggests a technique for assaying a sample for multiple analytes *simultaneously*.

Second, for this same reason, the combined teachings of Jackowski and Sawai do not teach or suggest each and every element of independent claim 1, from which each of claims 7 and 10-12 indirectly depends.

Further, Jackowski and Sawai both lack any teaching or suggestion of stimulating a light signal from a reactive element, which is indicative of a rate of reaction between the analyte of interest and the type of reactive element from which the light signal is stimulated, as required by claim 10.

For these reasons, reversal of the 35 U.S.C. § 103(a) rejections of claims 7 and 10-12 is respectfully requested.

#### VIII. CLAIMS APPENDIX

The current status of each claim that has been introduced into the above-referenced application is set forth in CLAIMS APPENDIX to this Appeal Brief.

IX. EVIDENCE APPENDIX

No evidence has been submitted pursuant to 37 C.F.R. §§ 1.130, 1.131, or 1.132.

Accordingly, no evidence appendix accompanies this Appeal Brief.

X. RELATED PROCEEDINGS APPENDIX

No decisions have been rendered by the Board or any court in a related proceeding/application. Therefore, this Appeal Brief is not accompanied by a related proceedings appendix.

XI. CONCLUSION

It is respectfully submitted that:

(A) The subject matter to which claims 1-6, 8, 9, 11, and 13-21 are directed is not anticipated under 35 U.S.C. § 102(e) by the disclosure of Jackowski; and

(B) Under 35 U.S.C. § 103(a), the subject matter to which claims 7 and 10-12 are directed is allowable over the teachings of Jackowski and Sawai.

For these reasons, it is respectfully requested that the 35 U.S.C. § 102(e) rejections of claims 1-21 be reversed and that each of these claims be allowed.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Brick G. Power". The signature is fluid and cursive, with the first name "Brick" being more prominent.

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**APPENDIX**

**CLAIMS**

1. (original) A method for performing an assay, comprising:  
substantially simultaneously evaluating the presence of a plurality of analytes in a sample,  
at least one analyte of the plurality of analytes having known parameters indicative of an acute  
metabolic or disease state;  
substantially simultaneously determining concentrations of each of the plurality of  
analytes in the sample;  
continuing the substantially simultaneous determination until the at least one analyte has  
been reliably determined to be present in an amount indicative of the metabolic or disease state;  
and  
reporting said reliable determination of the presence of the plurality of analytes in an  
amount indicative of the metabolic or disease state.
2. (previously presented) The method according to claim 1, wherein evaluating the  
presence of at least one other analyte in the sample continues after the report of the reliable  
determination of an amount indicative of the acute metabolic or disease state in order to  
accurately determine the presence or concentration of the at least one other analyte.
3. (original) The method according to claim 1, comprising evaluating binding of the  
plurality of analytes to corresponding reactive elements over a plurality of time points.

4. (original) The method according to claim 1, wherein the substantially simultaneous determination is effected by reacting at least one analyte of the plurality of analytes with a corresponding reactive element.

5. (original) The method according to claim 4, wherein the substantially simultaneous determination includes exposing the sample to the reactive elements corresponding to each analyte of the plurality of analytes.

6. (original) The method according to claim 5, wherein each reactive element is substantially immobilized on a waveguide surface.

7. (original) The method according to claim 4, wherein the continuation of the substantially simultaneous determination includes correlating a rate of reaction between the at least one analyte and the corresponding reactive element to a concentration of the at least one analyte.

8. (Currently amended) The method according to claim ~~7~~4, wherein the reactive elements are arranged in one or more patterns on ~~the~~ a waveguide surface.

9. (original) The method according to claim 4, wherein the substantially simultaneous determination includes introducing a light beam including at least one wavelength appropriate for

stimulating a light signal from the corresponding reactive element when the corresponding reactive element has coupled with the at least one analyte.

10. (original) The method according to claim 9, wherein the light signal is indicative of a rate of reaction between the analyte of interest and the corresponding reactive element.

11. (original) The method according to claim 10, wherein the substantially simultaneous determination includes measuring the light signal generated from the reaction of the at least one analyte with the corresponding reactive element.

12. (original) The method according to claim 10, wherein the continuation of the substantially simultaneous determination includes correlating a rate of reaction between the at least one analyte and the corresponding reactive element to a concentration of the at least one analyte.

13. (original) The method according to claim 1, wherein the at least one analyte is a marker released from cardiac tissue only after a myocardial infarction.

14. (original) The method according to claim 13, wherein the marker comprises myoglobin.

15. (original) The method according to claim 1, wherein the at least one analyte is a cardiac specific marker.

16. (original) The method according to claim 15, wherein the at least one analyte comprises troponin.

17. (original) The method according to claim 16, wherein the troponin comprises individual troponin subunits.

18. (original) The method according to claim 16, wherein the troponin comprises a complex including at least one troponin subunit.

19. (original) The method according to claim 16, wherein the troponin comprises at least one of native troponin and a modified troponin.

20. (original) The method according to claim 15, wherein the at least one analyte comprises creatine kinase.

21. (original) The method according to claim 20, wherein the creatine kinase comprises CK-MB.

22-35. (canceled)